

**REMARKS/ARGUMENTS**

Claims 1-24 remain in this application. New claim 24 has been added. Support for claim 24 can be found on page 24, lines 1-2 of the specification. Accordingly no issues of new matter are believed to be raised by the above amendments to the claims.

**REJECTION UNDER 35 USC 103**

**I**

Claims 1-4, 6-9, 11-13, and 20-21 were rejected under 35 USC 103(a) as being unpatentable over European Patent Application 429,842 (Hereinafter "Hai ('842)") in view of Us Patent No. 4,336,650 (hereinafter "Gorter"). See Pages 2-3 of the Office Action. Applicants respectfully disagree.

According to the Office Action "Hai ('842) discloses a method for transporting a molecule through a mammalian barrier membrane of at least one layer of cells comprising the steps of ablating the membrane. Furthermore, Hai ('842) discloses a wherein the shear member is a shear blade and wherein, the membrane is forced into the opening by pressure . . . ." See Page 2 of the Office Action. Applicants, however, cannot find such disclosure of "the membrane is forced into an opening by pressure" in Hai ('842). Rather, Hai ('842) merely discloses the use of an "electric razor." See, e.g., page 2, line 48, page 6, lines 12-13, and Examples 7-11 of Hai ('842)." Rather Hai ('842) is silent as to the design of razor to be used. However, it is likely a clipper-type razor that is often used to shave animals that does not comprise "a sheet containing at least one opening."

Hai ('842), thus, fails to disclose, or suggest, the specific sheer device disclosed in pending independent claim 1 which is a shear device comprising the element of "a sheet containing at least one opening." Hai et al., thus, also fails to disclose the method of using such a shear member such that "where said sheet is contacted with said membrane such that a portion of said membrane is forced through said opening and ablates said portion of said membrane exposed through said opening." In addition, Hai ('842) also fails to disclose, or suggest, the elements of "wherein said portion of said membrane is forced into said opening by a pressure force" as recited in dependent claim 3 and "wherein said shear member moves parallel to said shear sheet" as recited in dependent claims 20 and 21.

The Office Action admits that "Hai fails to explicitly disclose a sheet member, where the sheet is contacted with the membrane so that a portion of the membrane is forced through the opening and the shear member ablates the portion the membrane exposed through the perforated membrane. Gorter disclosed a similar method including a sheet member where a sheet (3) is contacted with a membrane so that a portion of the membrane is forced through the opening and the shear member (4) ablates the portion of the membrane exposed through the opening. . . ." See Page 3 of the Office Action. Applicants respectfully disagree. Applicants cannot find where Gorter discloses that the device is used to ablate a barrier membrane as recited in the claims. Rather, the device of Gorter is used to cut hair (e.g., col. 2, lines 57-59, which states that the openings are "hair entry apertures" and col. 3, lns. 49-40 which states "severs the hairs which protrude through the slots"). Further, the Office Action is silent as to why one of ordinary skill in the art would use the device of Gorter for the purpose set forth in Hai ('842) were Gorter is silent as to the use of the device to ablate the skin.

In addition, new claim 24 recites “wherein the area of at least one of said at least one opening is about 0.001 to 5 mm<sup>2</sup>.” Gorter is silent with respect to the area of the slots of its device. The size of the openings is important for tissue healing because the size of the wound opening will impact the time that it takes the wound to heal. Prior to wound healing, the membrane is susceptible to infection.

Accordingly, Applicants respectfully request that this rejection under 35 USC 102(b) be withdrawn.

## II

Claims 5 and 10 were rejected under 35 USC 103 as being unpatentable over Hai ('842) in view of Gorter and further in view of US Patent No. 5,441,490 (hereinafter “Svedman ('490)”). See pages 3-4 of the Office Action. Applicants again respectfully disagree. As discussed above Hai ('842) in view of Gorter fails to disclose, or suggest, the method of pending independent claim 1. Svedman ('490) is also silent with respect to the use of such a shear device. Rather, Svedman ('490) discloses the use of a pin to puncture the membrane. See, e.g., page 6, lines 4-6 of Svedman ('490). Thus, as Hai ('842) in view of Gorter and Svedman ('490) both fail to disclose, or suggest, the shear device, and consequently the use thereof, as recited in independent claim 1, these references also fail to disclose, or suggest the methods recited in dependent claims 5 and 10. Further, as Svedman ('490) relates to the use of a pin to pierce the skin, Applicants contend that one of ordinary skill in the art would not be lead to combine it with the shaving device of Hai('842). Accordingly, Applicants respectfully request that this rejection under 35 USC 103 be withdrawn.

## III

Claims 14 and 15 were rejected under 35 USC 103 as being unpatentable over Hai ('842) in view of Gorter and further in view of PCT Patent Application WO 89/01338 (hereinafter “McMichael”). See page 4 of the Office Action. According to the Office Action, “McMichael discloses a similar method in which a vaccine against Staphylococcus aureus is administered.” See Page 4 of the Office Action. Applicants again respectfully disagree. As discussed above Hai ('842) in view of Gorter fails to disclose, or suggest, the method of pending independent claim 1. McMichael is also silent with respect to the use of such shear device. Thus, as Hai ('842) in view of Gorter and McMichael both fail to disclose, or suggest, the shear device, and consequently the use thereof, as recited in independent claim 1, these references also fail to disclose, or suggest the methods recited in dependent claims 14 and 15. Accordingly, Applicants respectfully request that this rejection under 35 USC 103 be withdrawn.

## IV

Claims 16 and 17 were rejected under 35 USC 103 as being unpatentable over Hai ('842) in view of Gorter and further in view of US Patent No. 6,219,574 (hereinafter “Cormier et al. ('574)”). See pages 4-5 of the Office Action. According to the Office

Action, "Cormier et al. ('574) discloses a similar method in which a glucose molecule is transported out through the membrane." See page 4 of the Office Action. Applicants again respectfully disagree. As discussed above Hai ('842) fails to disclose, or suggest, the method of pending independent claim 1. Cormier et al. ('574) is also silent with respect to the use of such shear device. Thus, as Hai ('842) in view of Gorter and Cormier et al. ('574) both fail to disclose, or suggest, the shear device, and consequently the use thereof, as recited in independent claim 1, these references also fail to disclose, or suggest the methods recited in dependent claims 16 and 17. Further, as Hai et al. and Gorter do not disclose removing biological from the body following use of the electric razor, Applicants contend that one of ordinary skill in the art would not be lead to combine it with the electric razor of Hai('842) for the method set forth in Cormier et al. Accordingly, Applicants respectfully request that this rejection under 35 USC 103 be withdrawn.

## V

Claims 18, 19, and 20 were rejected under 35 USC 103 as being unpatentable over Hai ('842) in view of Gorter and further in view of US Patent No. 6,678,554 (hereinafter "Sun et al. ('554)"). See pages 5-6 of the Office Action. According to the Office Action, "Sun et al. ('554) describes a similar method in which an impedance sensor is used to measure the impedance of the barrier membrane." See page 5 of the Office Action. Applicants again respectfully disagree. As discussed above Hai ('842) in view of Gorter fails to disclose, or suggest, the method of pending independent claim 1. Sun et al. ('554) is also silent with respect to the use of such shear device. Thus, as Hai ('842) in view of Gorter and Sun et al. ('554) both fail to disclose, or suggest, the use recited in independent claim 1, these references also fail to disclose, or suggest the methods recited in dependent claims 16 and 17. Accordingly, Applicants respectfully request that this rejection under 35 USC 103 be withdrawn.

## VI

Claim 23 was rejected under 35 USC 103 as being unpatentable over Hai ('842) in view of Gorter and Sun et al. ('554) in further view of US Patent No. 4,406,658 (hereinafter "Lattin et al. ('658)"). See page 6 of the Office Action. According to the Office Action, "Lattin et al. ('658) describes a similar method in which a microprocessor received measurements from an impedance sensor." See page 6 of the Office Action. Applicants again respectfully disagree. As discussed above Hai ('842) in view of Gorter and Sun et al. ('554) both fail to disclose, or suggest, the method of pending independent claim 1. Lattin et al. ('658) is also silent with respect to the use of such shear device. Thus, as Hai ('842), Gorter, Sun et al. ('554), and Lattin et al. ('658) fail to disclose, or suggest, the shear device, and consequently the use thereof, as recited in independent claim 1, these references also fail to disclose, or suggest the method recited in dependent claim 23. Accordingly, Applicants respectfully request that this rejection under 35 USC 103 be withdrawn.

Serial No. 09/845,956

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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Date: December 7, 2006